



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/068,935	11/23/1998	DAVID PASCUAL	47714-5004	2851

7590 07/14/2003

REID G. ADLER
MORGAN, LEWIS & BOCKIUS, LLP
1800 M STREET, NW
WASHINGTON, DC 20036

EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 07/14/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	Examiner	Art Unit	

09/062935
GAMBEL
PASCUAL
1644

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 7/30/03

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 55-114 is/are pending in the application.

4a) Of the above claim(s) 60, 61, 65-66, 69-71, 73-75, 77-79, 81-84, 84-85, 88, 91-97, 107, 108, 110-114 is/are withdrawn from consideration.

5) ☐ Claim(s) 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90 is/are allowed.

6) ☒ Claim(s) 98-106, 109, 112-114 is/are rejected.

7) ☐ Claim(s) 98-106, 109, 112-114 is/are objected to.

8) ☐ Claim(s) 98-106, 109, 112-114 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on 7/30/03 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on 7/30/03 is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u> </u>
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u> </u>	6) <input type="checkbox"/> Other:

DETAILED ACTION

1. Applicant' amendment, filed 8/12/02 (Paper No. 21), has been entered.

The numbering of claims is not accordance with 37 C.F.R. 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 113-114 have been renumbered 112-113.

Claims 58, 62, 64, 105 and 109 have been amended.

Claims 112-113 have been added.

Applicant's election of an attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and Candida in Paper No. 17 has been acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.03(a)).

According to applicant, claims 55-90 and 95-111 correspond to the elected Group I.

See page 16 of applicant's election, filed 5/17/01 (Paper No. 17).

However, claims 95-97 read on kits comprising antibodies and not pathogen adhesins. Antibodies and pathogen adhesins differ in structure, physicochemical properties and modes of actions and are considered distinct.

As pointed out in the last Office Action (Paper No. 20), it appears that claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106 and 109 read on the elected invention an attachment molecules comprising proteins and glycoproteins, endothelial cells, mannose, selectin or integrin, ICAM-1 and Candida .

If does appear that applicant disagrees with this assessment of the claims that read on the elected invention.

Claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106, 109 and newly added claims 112-113 are being acted upon as the elected invention.

Claims 60, 61, 65, 66, 69-71, 73-75, 77-79, 81, 82, 84, 85, 88, 91-97, 107, 108, 110 and 111 have been withdrawn from consideration as being directed to a non-elected invention/species. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Claims 1-54 have been canceled previously.

It has been noted that vaccines appear to comprise a single active or critical element, namely the pathogen adhesin molecule.

Therefore, it appears that claims appear to be drawn to pathogens set forth in claims 73-83, regardless of the adhesion molecule on a host cell or extracellular matrix

Given that this may not have been applicant's intent, a Restriction was set forth in Paper No. 18, mailed 11/29/01, for the following reason.

Given the interpretation that the claims read on the active or critical element of the pathogens set forth in claims 73-83, these pathogens and immunogenic fragments thereof, differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. For example, the vaccines encompass a broad, diverse and structural distinct spectrum of pathogens.

In the Interview Summary on 11/29/01 (Paper No. 19), the examiner indicated that a first action on the merits would be forthcoming based upon the election set forth in Paper No. 17.

The examiner apologizes for any inconvenience to applicant in this matter.

Again, it is noted that the claims appear to simply read on well known vaccine formulations of a broad spectrum of pathogens at the time the invention was made.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 8/12/02 (Paper No. 21). The rejections of record can be found in the previous Office Action (Paper No. 20).
3. Drawings submitted on 8/12/02 (Paper No. 23) comply with 37 CFR 1.84.

4. Applicant's amendment, filed 8/12/02 (Paper No. 21), indicates that an Abstract was submitted on page 93 in the instant application. However, the examiner could not locate page 93.

Therefore, applicant is required to provide the Abstract of the Disclosure as required by 37 CFR 1.72(b) on a separate sheet, which reads on the claimed invention.

If applicant intends to rely upon the original submission on page 93, then applicant should provide evidence that page 93 was filed with the application as-filed.

However, simply providing an Abstract on a separate sheet would suffice.

5 The amendment filed 8/12/02 (Paper No. 21), is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

The added material which is not supported by the original disclosure is as follows:

the corrections to Table 1 at page 16, particularly the corrections to P-selectin, ICAM-1 and LFA-1. It appears that applicant is changing the responses from that which was disclosed in the application as-filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Alternatively, applicant is invited to provide sufficient direction for the support of these changes in the specification as filed.

6. Claims 55-59, 62-64, 67, 68, 72, 76, 80, 83, 86, 87, 89, 90, 98-106, 109 and newly added claims 112-113 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cutler et al. (U.S. Patent No. 5,578,309) (see previous 892, mailed 10/9/01 in Paper No. 18) alone as well as acknowledged by applicant's disclosure on page 2, paragraphs 1-2 of the specification as set forth in the previous Office Action (Paper No. 20.).

Applicant's arguments, filed 8/12/02 (Paper No. 23), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submit that the specification of the instant application has been amended to indicate that the present application is a continuation-in-part of the application that issued as U.S. Patent No. 5,578,039 and, in turn, the '309 patent cannot be cited as art against the present application.

In contrast to applicant's assertions, U.S. Patent No. 5,578,309 is "by another" (See MPEP 2136.04) and the priority date of the instant claims, based upon written description, does not precede the priority 102(e) date of U.S. Patent No. 5,578,309. Therefore, U.S. Patent No. 5,578,309 stands as prior art.

Applicant's arguments are not found persuasive.

7. No claim allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
October 29, 2002